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Please find below and/or attached an Office communication concerning this application or proceeding.

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/538,715
Filing Date: June 14, 2005
Appellant(s): FARDEAU ET AL.

B. J. Sadoff
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 12, 2010 appealing from the Office action mailed January 12, 2010.

(1) Real Party in Interest

The examiner has no comment on the statement, or lack of statement, identifying by name the real party in interest in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The following is a list of claims that are rejected and pending in the application:

Claim 12

(4) Status of Amendments After Final

The examiner has no comment on the appellant's statement of the status of amendments after final rejection contained in the brief.

(5) Summary of Claimed Subject Matter

The examiner has no comment on the summary of claimed subject matter contained in the brief.

(6) Grounds of Rejection to be Reviewed on Appeal

The examiner has no comment on the appellant's statement of the grounds of rejection to be reviewed on appeal. Every ground of rejection set forth in the Office action from which the appeal is taken (as modified by any advisory actions) is being maintained by the examiner except for the grounds of rejection (if any) listed under the subheading "WITHDRAWN

REJECTIONS.” New grounds of rejection (if any) are provided under the subheading “NEW GROUNDS OF REJECTION.”

(7) Claims Appendix

The examiner has no comment on the copy of the appealed claims contained in the Appendix to the appellant’s brief.

(8) Evidence Relied Upon

No evidence is relied upon by the examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim 12 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claim is directed to an isolated bacterial strain of an *Exiguobacterium* lactigenes comprising a 16S rRNA sequence of SEQ ID NO:1 and a DNA sequence at least 70% of which being capable of hybridizing with genomic or plasmid DNA of the strain deposited under No. I-2962 with the Collection Nationale de Cultures de Microorganismes (strain 10C), and the isolated strain has properties of thermoresistant, saccharolytic, and/or amylolytic, producing L(+) lactate, growth properties at temperatures of 40-50°C, at pH 5.4-9.15 and a guanine and cytosine content being approximately 50 mol% .

The scope of the claimed strain is extremely broad encompassing not only the strain deposited under No. I-2962, but also any mutant and/or variant of the strain (I-2962) having 16S

rRNA of SEQ ID NO:1 and at least of 70% of ANY segment of DNA sequences capable of hybridizing with the genomic or plasmid DNA of I-2962 strain.

The specification discloses only the deposited strain with deposit No. I-2962 (or strain 10C) which possesses the claimed functional properties and growth characteristics. The specification stated that the scope of the invention comprises the mutants of the strain conserving at least a 70% capacity for hybridization with the genomic DNA of the deposited strain (p. 3, lines 34-38). The specification does not provide any example of such mutants and/or variants having the claimed functional properties and growth characteristics (i.e. thermoresistant, saccharolytic, or amylolytic; producing L(+) lactate; having growth properties at temperatures of 40-50°C, at pH 5.4-9.15; and a guanine and cytosine content being approximately 50 mol%).

It is understood that one of ordinary skill in the art can identify bacteria having the sequences of SEQ ID NO:1 as a 16S rRNA based on the sequence and at least 70% of any DNA segment of the bacteria capable of hybridizing under any condition (e.g. either high or low stringent condition) to the genomic or plasmid DNA of the deposited strain (strain 10C; I-2962). However, it is construed that not all of those identified bacteria would have the claimed properties. Thus, a person of ordinary skill in the art would need to further identify those which have the claimed properties. However, the specification failed to provide any disclosure relating similarity of structure (sequences/domains) to conservation of function. The structural characteristics given to the isolated bacteria are SEQ ID NO:1 and at least 70% of ANY part of DNA of the isolated bacteria can hybridize (at any condition) to the DNA of the deposited strain of No. I-2962. There is no disclosure of other information in the specification related to relate the structure to the functional properties of the claimed invention.

Without recognized correlation between structure and function, a person of ordinary skill in the art would not be able to identify without further testing which of those isolated bacteria possessing SEQ ID NO:1 and at least 70% of any DNA sequence being capable of hybridizing to the DNA of deposited strain.

Therefore, those of ordinary skill in the art would not consider the Appellant to have been in possession of the claimed genus of isolated bacterium on the single species disclosed, and thus, it is concluded that the specification does not provide written description in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the entire scope of the claimed invention other than the deposited strain (I-2962).

M.P.E.P. §2163 states “To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116.”

M.P.E.P. § 2163 also recites, “An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention... one must define a compound by ‘whatever characteristics sufficiently distinguish it’. A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process.” and further, “The description needed to satisfy the requirements of 35 U.S.C. 112

"varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence." *Capon v. Eshhar*, 418 F.3d at 1357, 76 USPQ2d at 1084.< Patents and printed publications in the art should be relied upon to determine whether an art is mature and what the level of knowledge and skill is in the art. In most technologies which are mature, and wherein the knowledge and level of skill in the art is high, a written description question should not be raised for claims >present in the application when originally filed,< even if the specification discloses only a method of making the invention and the function of the invention. See, e.g., *In re Hayes Microcomputer Products, Inc. Patent Litigation*, 982 F.2d 1527, 1534-35, 25 USPQ2d 1241, 1246 (Fed. Cir. 1992) ("One skilled in the art would know how to program a microprocessor to perform the necessary steps described in the specification. Thus, an inventor is not required to describe every detail of his invention. An applicant's disclosure obligation varies according to the art to which the invention pertains. Disclosing a microprocessor capable of performing certain functions is sufficient to satisfy the requirement of section 112, first paragraph, when one skilled in the relevant art would understand what is intended and know how to carry it out."). In contrast, for inventions in emerging and unpredictable technologies, or for inventions characterized by factors not reasonably predictable which are known to one of ordinary skill in the art, more evidence is required to show possession."

(10) Response to Argument

Appellant argued that the Examiner has failed to overcome the "strong presumption" that an adequate written description of the claimed invention is present when the application is filed citing M.P.E.P. §2163.

As discussed in the claim rejection, the subject matter of claim 12 is directed to an isolated bacterium having 16S rRNA of SEQ ID NO:1, and at least of 70% of ANY segment of the isolated bacterium's DNA capable of hybridizing to the DNA of the deposited strain of No. I-2962 (or strain 10C), and the isolated strain of bacteria should necessarily possess the properties of thermoresistant, saccharolytic, or amylolytic; producing L(+) lactate; having growth properties at temperatures of 40-50°C, at pH 5.4-9.15; and a guanine and cytosine content being approximately 50 mol%.

A person of ordinary skill in the art would certainly identify a strain of bacteria having SEQ ID NO:1, and having at least 70% of any part of its DNA hybridizing at any condition to the DNA of the deposited strain of No. I-2962, and those identified would be considered either mutants or variants of the deposited strain. However, these identified strains do not necessarily possess the claimed properties. There is no description in the specification how a person of ordinary skill in the art would identify genetic structure related to the proposed function. There is no known art-recognized structure-function correlation or pre-existing knowledge for a person of ordinary skill in the art to identify strains possessing the claimed properties.

The limitation of "at least 70% of which (a DNA) is capable of hybridizing with the genomic or plasmid DNA of the strain deposited...No. I-2962," is extremely broad. This limitation is interpreted as any DNA of any size from the isolated strain can hybridize under any stringent condition to the genomic or plasmid DNA of the deposited strain of No I-2962, and this does not provide sufficient structural limitation to the strain. Even if this is interpreted as the isolated strain possesses at least 70% sequence identity to the deposited strain of No. I-2962, the specification does not provide any guidance where in the genomic DNA of the deposited strain

such modification (i.e. mutation and/or variation) up to 30% can be introduced or present without losing the claimed properties.

Without knowing such structure-function correlation, one skilled in the art has burden to screen each and every possible strain having SEQ ID NO:1 and capable of hybridizing to the genomic or plasmid DNA of the strain under No. I-2962 for the claimed properties.

Appellant further alleged that the determination of what is needed to support generic claims to biological subject matter depends on a variety of factors such as the existing knowledge in the particular field, the extend and content of the prior art, the maturity of the science of technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter. Appellant asserted that it is unnecessary for the specification to provide a description of proteins which are already known in the prior art.

The Examiner respectfully disagrees with this conclusion. The issue raised in the instant claim rejection cannot be analyzed the same way as the description of previously known in the art. As disclosed in the specification, the deposited strain is new, and there is no knowledge available in the prior art with regard to the deposited strain. It is understood that the claimed properties belong to the deposited strain of No. I-2962 (strain 10C) according to the specification (p.8), however, there is no information in the art or in the specification which DNA structure of this newly isolated strain is responsible for the claimed properties and characteristics.

Appellant alleged that there has been evidence provided to demonstrate that the recitation of 70% hybridization of claim 12 is commonly accepted by scientist and those of ordinary skill in the art as a description of related strains citing Wayne et al., and that one of ordinary skill in the art will appreciate that this characteristic of the claimed strains along with the additionally

recited characteristics of the claimed invention are sufficient to conclude that the applicants were in possession of the claimed invention at the filing date of the application.

The teaching of Wayne et al. is directed the method of bacterial taxonomy to determine species, and the phylogenetic definition of a species generally would include strains with approximately 70% or greater DNA-DNA relatedness and with 5°C or less ΔT_m (p. 463, right col.).

It is believed that such DNA-DNA relatedness of approximately 70% or greater is based on the entire genomic DNA of the strain, rather than any DNA fragment with any size obtainable from the strain as claimed in the instant invention.

Furthermore, even if it is considered that the DNA fragment of the limitation is genomic DNA of the isolated strain, there is no specific condition given in the claim or the specification for DNA-DNA hybridization. As disclosed by Wayne et al., not only 70% or more DNA relatedness AND 5°C or less ΔT_m must be considered (p.463, right col.). However, the current application fails to disclose such requirement or condition in the claims, and thus, merely having at least 70% of any DNA fragment capable to hybridize the genomic or plasmid DNA of the strain 10C does not necessarily qualify the isolated strain as the same species.

Still further, even if one of skilled in the art can identify and/or isolate strains satisfying both requirements of having SEQ ID NO:1 and at least 70% of "genomic" DNA of the strains capable of hybridizing to the genomic or plasmid DNA of the strain 10C, thus the same species as strain 10C, which is consistent with the Examiner's acknowledgement in the previous OA that one of skilled in the art could find strains (thus, exist) classified as the same "phylogenetic species" as strain 10C, this would not necessarily meet the functional requirements (functional

properties and growth characteristics) claimed in the current invention. The specification failed to disclose how to identify strains having such properties and characteristics, and how DNA sequences/domains in genomic structure of the strain are related to the claimed functional properties and growth characteristics of the strain. Without such relationship between genetic structure and functional properties/growth properties, one of skilled in the art would not be able to identify which strains would possess the claimed functional properties and growth characteristics as claimed.

Appellant discussed Enzo Biochem v. Gen-Probe, Inc., 63 USPQ2d 1609, 1613 (Fed. Clarification is required. 2002) with regard to the correlation between function and structure, and alleged that 70% hybridization requirement of the instant invention would be appreciated by one of ordinary skill to be related to the additionally recited functional characteristics of the claimed strains, as evidenced by, for example, Wayne et al. This argument has been discussed above, and concluded that the limitation in the claims and disclosure in the specification of the instant application failed to disclose any relationship between structure and function, and it is the Examiner's position that there is no such relationship disclosed in the specification or known in the art.

Finally, Appellant discussed In re Kenneth Alonso 88 USPQ2d 1849, 1852 (Fed. Clarification is required. 2008) with regard to the written description of genus, and alleged that the applicants have described and deposited a representative species, described representative sequence of the 16S rRNA required by the claimed strains and described a combination of physical and chemical properties as well as functional characteristics of the claimed strains, and thus one of ordinary skill will appreciate that the applicants were in possession of the claimed

invention at the time the application was filed.

The Examiner does not repudiate that one of skilled in the art would identify and isolate the strains having 16S rRNA of SEQ ID NO:1 and at least 70% of a DNA of the strains capable hybridizing the genomic or plasmid DNA of the strain 10C (deposited representative strain) as discussed above. Again, the question here is whether there is sufficient description in the specification and/or known in the art that one of skilled in the art would identify the claimed strains having claimed function properties and growth characteristics without further testing among those strains having 16S rRNA of SEQ ID NO:1 and at least 70% of a DNA of the strains capable hybridizing the genomic or plasmid DNA of the strain 10C.

The Examiner articulated throughout the response that it is concluded that there is no disclosure in the specification or knowledge known in the art to guide one of skilled in the art to determine what kind of DNA sequence structures are required for the claimed properties and growth characteristics, which sequence domains should be conserved to possess the claimed properties, or how much of mutations and/or modification can be introduced to what region or domain of genomic or plasmid DNA of the strain, without losing the claimed functional properties and growth characteristics. Without such description, those of ordinary skill in the art would not consider the appellant to have been in possession of the claimed genus of bacteria strains on the single species disclosed.

In conclusion, it is considered that the instant application failed to provide written description in such a way as to reasonably convey to one skilled in the relevant art that the appellant, at the time the application was filed, had possession of the claimed invention.

(11) Related Proceeding(s) Appendix

Art Unit: 1651

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Taeyoon Kim/

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